

A3  
cont.

14. (Amended) A method of forming a hydrogel wound dressing, comprising the [steps:] step of applying a composition to a wound via spray, wherein the composition comprises water soluble PVA macromers having one or more pendant crosslinkable groups and the macromers crosslink to form a hydrogel on the wound [; and bringing a gelling stimulus into contact with the composition, either before, during, or after application of the composition to the wound, causing formation of the hydrogel wound dressing].

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22. (Amended) The method of claim 21, wherein the active agent is selected from the group consisting of growth factors [(e.g. platelet-derived growth factor, epidermal growth factor, transforming growth factor beta (TGF- $\beta$ ))], nitric oxide, antibiotics, anti-inflammatories, analgesics, blood coagulants, and enzymes.

A5

25. (Amended) The method of claim 14, wherein the *in situ* crosslinking [polymerization] is in response to redox initiation.

## REMARKS

### Claim Amendments

Claim 1 has been amended to include the limitations of claims 5 and 12. Claim 14 has been amended to include the limitations of claims 18 and 24. Claims 9, 13, 22, and 25 have been amended for clarity and to correct claim dependency. The amendments have proper support since they simply rewrite original claims in independent form (claims 1 and 14) and incorporate no new matter.

### The Office Action

Claims 6, 9, 12, 13, 19, 22, and 25 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite.

Claims 1-4, 6, 8, 9, 14-17, 19, 21, 22, and 26 were rejected under 35 U.S.C. 102(b) for being anticipated by EP 560 014 ("EP '014").

Claims 1, 3, 4, 8, 9, 14, 16, 17, 21, 22, and 26 were rejected under 35 U.S.C. 102(b) for being anticipated by U.S. Patent No. 4,495,168 ("US '168").

Claims 1-8, 13-21, 25, and 26 were rejected under 102(e) for being anticipated by U.S. Patent No. 6,179,862 ("US '862").

Claims 1-26 were rejected under 103(a) as being obvious over any of EP '014, US '168, or US '862.

Claims 1-26 were rejected under 103(a) as being obvious over any of EP '014, US '168, or US '862 in view of U.S. Patent No. 5,410,016 ("US '016").

### **ANALYSIS**

#### **Rejections Under 35 U.S.C. 112, second paragraph**

##### Claims 6 and 19

Claims 6 and 19 are cancelled, rendering this objection moot.

##### Claims 9 and 25 (sic)

The material in parentheses in claims 9 and 22 has been deleted.

##### Claim 12

This rejection is moot due to amendments.

##### Claims 13 and 25

The term "crosslinking" in renumbered claims 13 and 25 has proper antecedent basis.

#### **Rejections Under 35 USC 102(b) and (e)**

##### *EP 560 014 ("EP '014")*

Claims 1-4, 6, 8, 9, 14-17, 19, 21, 22, and 26 were rejected under 35 U.S.C. 102(b) over EP 560 014. Independent claims 1 and 14 have been amended to include the limitations of claims 5 and 12 (for claim 1) and 18 and 24 (for claim 14). Thus this rejection is moot.

##### *U.S. Patent No. 4,495,168 ("US '168")*

Claims 1, 3, 4, 8, 9, 14, 16, 17, 21, 22, and 26 were rejected under 35 U.S.C. 102(b) over US '168. Independent claims 1 and 14 have been amended to include the limitations of claims 5 and 12 (for claim 1) and 18 and 24 (for claim 14). Thus this rejection is moot.

##### *U.S. Patent No. 6,179,862 ("US '862")*

Claims 1-8, 13-21, 25, and 26 were rejected under 102(e) over US '862. Independent claims 1 and 14 have been amended to include the limitations of claims 5 and 12 (for claim 1) and 18 and 24 (for claim 14). Thus this rejection is moot.

**Rejections Under 35 USC 103**

*EP '014, US '168, or US '862*

Claims 1-26 were rejected under 103(a) as being obvious over any of EP '014, US '168, or US '862. The Examiner acknowledges that the references do not teach the PVA macromer. However, the Examiner further states that a formulation comprising macromers would be obvious since "PVA is inherently a crosslinkable biodegradable macromer". Applicants disagree that PVA is considered by one skilled in the art to be a macromer. However, this point does not need to be argued since the claims have been more specifically amended to include the limitations previously in claims 12 and 24 that the macromers are "water soluble PVA macromers having one or more pendant crosslinkable groups". Such macromers are not taught or suggested in the cited references.

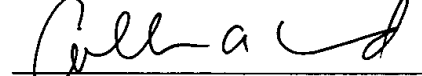
*EP '014, US '168, or US '862 in view of U.S. Patent No. 5,410,016 ("US '016")*

Claims 1-26 were rejected under 103(a) as being obvious over any of EP '014, US '168, or US '862 in view of U.S. Patent No. 5,410,016 ("US '016"). Again, the Examiner acknowledges that the references do not teach the PVA macromer. However, the Examiner further states that a formulation comprising macromers would be obvious since "PVA is inherently a crosslinkable biodegradable macromer". Applicants disagree that PVA is considered by one skilled in the art to be a macromer. However, this point does not need to be argued since the claims have been more specifically amended to include the limitations previously in claims 12 and 24 that the macromers are "water soluble PVA macromers having one or more pendant crosslinkable groups". Such macromers are not taught or suggested in the cited references.

Conclusion

It is respectfully submitted that the references are not appropriate as the basis of rejection of the claims.

Respectfully submitted,



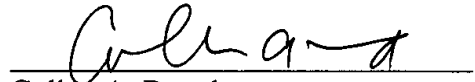
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Date: June 11, 2003

### Claims Showing Amendments

1. (Amended) A hydrogel wound dressing formed by spray delivery of a liquid composition to the wound, wherein the composition comprises water soluble PVA macromers having one or more pendant crosslinkable groups and the macromers crosslink to form [forms] a hydrogel *in situ* on the wound.
2. The wound dressing of claim 1, wherein the hydrogel is degradable.
3. The wound dressing of claim 1, wherein the composition is delivered via an aerosol delivery device.
4. The wound dressing of claim 1, wherein the composition is delivered via a pump spray delivery device.
5. Cancelled.
6. Cancelled
7. Cancelled
8. The wound dressing of claim 1, wherein the composition further contains one or more additives selected from the group consisting of preservatives, biologically active agents, defoamers, wettings agents, leveling agents, hydrating agents, thickeners, fillers, and absorbents.
9. (Amended) The wound dressing of claim 8, wherein the active agent is selected from the group consisting of growth factors [(e.g. platelet-derived growth factor, epidermal growth factor, transforming growth factor beta (TGF- $\beta$ ))], nitric oxide, antibiotics, anti-inflammatories, analgesics, blood coagulants, and enzymes.
10. The wound dressing of claim 8, wherein the active agent is one which delivers NO to the wound.
11. The wound dressing of claim 1, wherein the dressing debrides the wound when it is removed.
12. Cancelled
13. (Amended) The wound dressing of claim 1 [6], wherein the *in situ* crosslinking is in response to redox initiation.

14. (Amended) A method of forming a hydrogel wound dressing, comprising the [steps:] step of applying a composition to a wound via spray, wherein the composition comprises water soluble PVA macromers having one or more pendant crosslinkable groups and the macromers crosslink to form a hydrogel on the wound [; and

bringing a gelling stimulus into contact with the composition, either before, during, or after application of the composition to the wound, causing formation of the hydrogel wound dressing].

15. The method of claim 14, wherein the hydrogel is degradable.

16. The method of claim 14, wherein the composition is delivered via an aerosol delivery device.

17. The method of claim 14, wherein the composition is delivered via a pump spray delivery device.

18. Cancelled.

19. Cancelled.

20. Cancelled.

21. The method of claim 14, wherein the composition further contains one or more additives selected from the group consisting of preservatives, biologically active agents, defoamers, wettings agents, leveling agents, hydrating agents, thickeners, fillers, and absorbents.

22. (Amended) The method of claim 21, wherein the active agent is selected from the group consisting of growth factors [(e.g. platelet-derived growth factor, epidermal growth factor, transforming growth factor beta (TGF- $\beta$ ))], nitric oxide, antibiotics, anti-inflammatories, analgesics, blood coagulants, and enzymes.

23. The method of claim 21, wherein the active agent is one which delivers NO.

24. Cancelled.

25. (Amended) The method of claim 14, wherein the *in situ* crosslinking [polymerization] is in response to redox initiation.

26. Cancelled

**Clean Copy of Claims as Amended**

1. (Amended) A hydrogel wound dressing formed by spray delivery of a liquid composition to the wound, wherein the composition comprises water soluble PVA macromers having one or more pendant crosslinkable groups and the macromers crosslink to form a hydrogel *in situ* on the wound.
2. The wound dressing of claim 1, wherein the hydrogel is degradable.
3. The wound dressing of claim 1, wherein the composition is delivered via an aerosol delivery device.
4. The wound dressing of claim 1, wherein the composition is delivered via a pump spray delivery device.
8. The wound dressing of claim 1, wherein the composition further contains one or more additives selected from the group consisting of preservatives, biologically active agents, defoamers, wettings agents, leveling agents, hydrating agents, thickeners, fillers, and absorbents.
9. (Amended) The wound dressing of claim 8, wherein the active agent is selected from the group consisting of growth factors, nitric oxide, antibiotics, anti-inflammatories, analgesics, blood coagulants, and enzymes.
10. The wound dressing of claim 8, wherein the active agent is one which delivers NO to the wound.
11. The wound dressing of claim 1, wherein the dressing debrides the wound when it is removed.
12. Cancelled
13. (Amended) The wound dressing of claim 1, wherein the *in situ* crosslinking is in response to redox initiation.
14. (Amended) A method of forming a hydrogel wound dressing, comprising the step of applying a composition to a wound via spray, wherein the composition comprises water soluble PVA macromers having one or more pendant crosslinkable groups and the macromers crosslink to form a hydrogel on the wound.
15. The method of claim 14, wherein the hydrogel is degradable.
16. The method of claim 14, wherein the composition is delivered via an aerosol delivery device.

17. The method of claim 14, wherein the composition is delivered via a pump spray delivery device.

21. The method of claim 14, wherein the composition further contains one or more additives selected from the group consisting of preservatives, biologically active agents, defoamers, wettings agents, leveling agents, hydrating agents, thickeners, fillers, and absorbents.

22. (Amended) The method of claim 21, wherein the active agent is selected from the group consisting of growth factors, nitric oxide, antibiotics, anti-inflammatories, analgesics, blood coagulants, and enzymes.

23. The method of claim 21, wherein the active agent is one which delivers NO.

25. (Amended) The method of claim 14, wherein the *in situ* crosslinking is in response to redox initiation.